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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,137	08/29/2001	Christopher M. Angelucci	8932-538	6603

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EXAMINER	
PRIDDY, MICHAEL B	
ART UNIT	**PAPER NUMBER**
3733	

MAIL DATE	DELIVERY MODE
10/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/942,137	ANGELUCCI ET AL.	
	Examiner	Art Unit	
	Michael B. Priddy	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,13-21,23-25,27 and 53-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8,13-21 and 69-71* is/are allowed.

6)☒ Claim(s) *23-25,27,53-60,63-68 and 72-74* is/are rejected.

7)☒ Claim(s) *61 and 62* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 23-25, 53-55, 58, 63, 65-67 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich et al. (U.S. 5,458,638). Kuslich et al. teach an implant for use in a patient's spinal column, the implant comprising: a tubular body having a length, a width, a depth, a longitudinal axis, and an outer surface and an inner surface forming a thin tubular wall, the perimeter of the outer surface having a substantially oval, circular, or elliptical shape, the body further having first and second ends orthogonal to the longitudinal axis, at least one of the first and second ends comprising a cutout 132 configured to engage and retain a bone segment, the cutout 132 comprising a centerline running parallel to the implant longitudinal axis dividing the ends, the centerline of the at least one cutout 132 being offset from the longitudinal axis; the at least one cutout 132 has a substantially concave arcuate shape AS which is angled elative to flat face FF; the perimeter of the outer surface of the implant being substantially elliptical; further comprising at least one surface 130 defining a hole in communication with said outer surface and said inner surface, suitable for attaching a suture to secure said implant to at least one of said first and second bone segments; wherein the implant is fabricated of biocompatible metal (titanium recited in lines 44-45

of column 8); wherein the second end also comprises a cutout CO having a substantially concave arcuate shape AS (see Fig. 14 below).

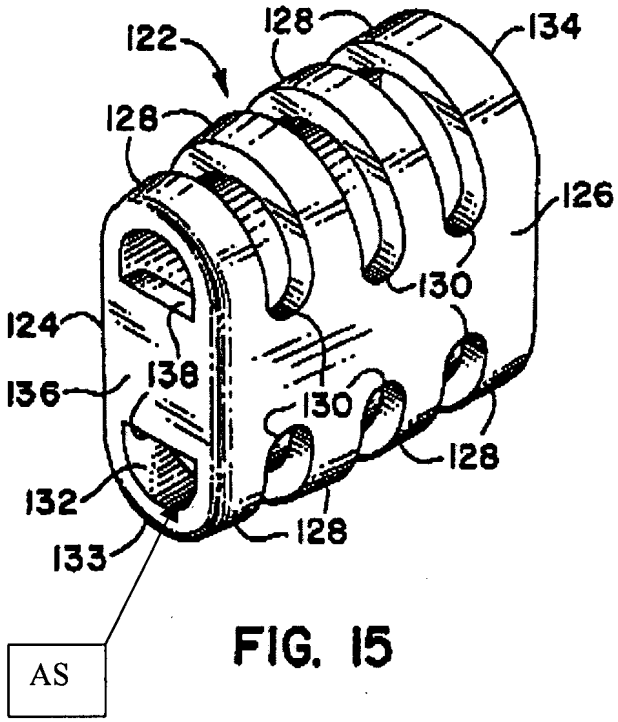

FIG. 15

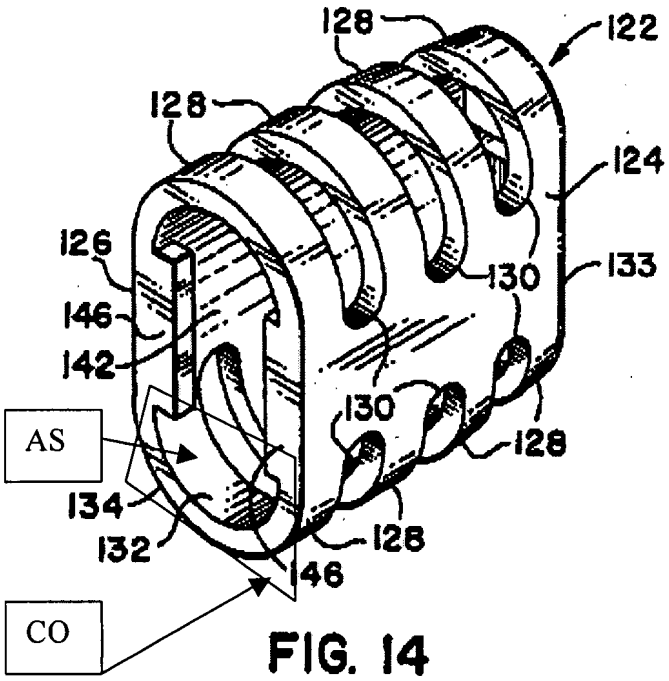

FIG. 14

Claims 53 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Ray et al (U.S. 5,026,373). Ray et al. teach an implant 10 for use in a patient's spinal column, said implant 10 comprising: a body portion having a length, a width, a depth and a longitudinal axis, and configured to be insertable between first and second cut bone segments, the body portion having an outer surface and an inner surface defining a substantially hollow portion, the body portion further having first and second ends 16 open to said hollow portion and orthogonal to said longitudinal axis, at least one of the first and second ends 16 comprising a cutout 18 (any of those apertures not centered in endplate 16) configured to engage and retain at least one of the first and second cut bone segments, the cutout 18 comprising a centerline running parallel to the implant

longitudinal axis dividing said ends 16, wherein the centerline of the at last one cutout 16 is offset from the longitudinal axis; and wherein the perimeter of the outer surface of the implant 10 is a circle.

Claim Rejections - 35 USC § 103

Claims 57, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. as applied to claims 53 and 72 above, and further in view of the following. Kuslich et al. teach all of the limitations of the present invention except the length ranging from about 11.5 to about 15.5 millimeters, the width ranges from about 8 to about 9 millimeters and the depth ranges from about 5.5 to about 6.5 millimeters and wherein the tubular wall has a thickness of about 1 millimeter.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Kuslich et al. such that the length ranges from about 11.5 to about 15.5 millimeters, the width ranges from about 8 to about 9 millimeters and the depth ranges from about 5.5 to about 6.5 millimeters and wherein the tubular wall has a thickness of about 1 millimeter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 27 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. as applied to claims 23 and 53 above, and further in view of Paul et

al. (U.S. 6,258,125). Kuslich et al. teach all of the limitations of the present invention except the implant being formed of bone allograft material.

Paul et al. teach a related intervertebral spacer comprised of allograft bone material. It would have been obvious to one having ordinary skill in the art at the time of the present invention to have formed the implant of Kuslich et al. of allograft bone material because allograft has similar mechanical properties to those of vertebrae and would therefore prevent stress shielding.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. in view of Paul et al. as applied to claim 59 above, and further in view of the following. The combination taught by Kuslich et al. in view of Paul et al. teaches all of the imitations of the present invention except at last a portion of at least one of said first and second ends is comprised of demineralized cortical bone.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use demineralized, cortical, allograft bone to construct the entire device of the combination of Kuslich et al. in view of Paul et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. as applied to claim 53 above, and further in view of the following. Kuslich et al.

teach all of the limitations of the present invention except the implant being formed of a biocompatible polymer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to for the implant of Kuslich et al. of a biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Allowable Subject Matter

Claims 1-8, 13-21 and 69-71 are allowed.

Claims 61 and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 23-25, 27, 53-60, 63-68 and 72-74 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is 571-272-2243. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael B. Priddy
October 11, 2007

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER